1 of 2

K091035

510(k) Summary
Full Breath Sleep Appliance Lower

JUN 24 2009

Applicant

Bryan Keropian DDS
18663 Ventura Blvd., Suite 200
Tarzana, CA 91356

Product Name

Full Breath Sleep Appliance Lower

Proposed Product Code

LQZ

510(k) # of device being modified

K061228

Proposed Device Classification

Jaw Repositioning Device

Contact Person

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510(k) Application Preparation

Bryan Keropian, DDS

K091035

510(k) Summary (continued)

This is a change in usage to the Full Breath Posterior Tongue Restrainer FBPTR (K061228). The FBPTR is for usage on the maxillary arch. The Full Breath Solution Lower FBSL is the same appliance (FBPTR) turned over and placed on the lower arch. All the research and data gathered for 510(k) K061228 are applicable for this application for certification. In addition, It is being utilized with the added the tongue depression technique to open the oropharyngeal airway. The net result is eradication of snoring and reduction of AHI.

DEVICE SPECIFICATIONS

The Full Breath Soution Lower is a custom fabricated device which is typically done by a professional dental laboratory and delivered by a dentist.

PREDICATE DEVICE COMPARISON TABLE:

Product Name	Quiet Night Quite Nt. MA	Full Breath Sleep Appl. FBAB	Full Breath Sleep Appl. FBPB	Full Breath Sleep Appl. FBPTR
510(k)	K032410	K052862	KO53065	K061228
Product Code	LQZ	LQZ	LQZ	LQZ
Indicated Use	Treatment of Mild & Mod. OSA Treatment of Snoring	Treatment of Mild & Mod. OSA Treatment of snoring	Treatment of Mild & Mod OSA Treatment of snoring	Treatment of Mild & Mod OSA Treatment of snoring
Method of Delivery	By prescription	By prescription	By prescription	By prescription

INDICATIONS FOR USE

1. An oral appliance to be used for the treatment of mild and moderate Obstructive Sleep Apnea.
2. An oral appliance to be used for the treatment of snoring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2009

Bryan Keropian, D.D.S.
Operation Manager
Bryan Keropian DDS
18663 Ventura Boulevard, Suite 200
Tarzana, California 91356

Re: K091035
Trade/Device Name: Full Breath Sleep Appliance Lower
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LQZ
Dated: April 3, 2009
Received: April 10, 2009

Dear Dr. Keropian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091035

Indications for Use

510(k) Number (if known):

Device Name: Full Breath Sleep Appliance Lower

Indications For Use:

1. Full Breath Sleep Appliance Lower– This appliance is indicated for the treatment of snoring.
2. Full Breath Sleep Appliance Lower – This appliance is indicated for the treatment of mild to moderate obstructive sleep apnea.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091035